UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MASTER FILE
	06-MD-1789-JFK
This Document Relates to: Shirley Boles v. Merck & Co., Inc. Case No. 1:06-cv-09455-JFK	**OPINION & ORDER**

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JOHN F. KEENAN, United States District Judge:

This case was selected by the Plaintiffs' Steering Committee as a bellwether case in this multidistrict products liability litigation concerning Defendant Merck Sharpe & Dohme Corp.'s ("Merck" or "Defendant") prescription drug Fosamax. The case went to trial in August 2009 and ended in a mistrial after

the jury could not reach a unanimous verdict. The contentious re-trial in June 2010 culminated with an $8 million verdict for Plaintiff Shirley Boles ("Plaintiff" or "Boles"). Before the Court are Merck's motions for judgment as a matter of law and for a new trial under Rules 50 and 59 of the Federal Rules of Civil Procedure. For the reasons that follow, the motions are denied. Although the Court does not believe that a new trial is warranted, it finds that the $8 million damage award is excessive and thus orders a remittitur sua sponte.

I. BACKGROUND

Merck manufactures and distributes Fosamax (alendronate), a drug widely prescribed for the treatment and prevention of osteoporosis. Fosamax belongs to a class of drugs called bisphosphonates, which have become standard treatment for various metabolic and oncologic diseases related to abnormalities in the bone remodeling cycle. The primary effect of Fosamax is the inhibition of bone resorption, which in turn decreases bone formation and remodeling.

The Food & Drug Administration ("FDA") approved Fosamax in 1995 for the treatment of osteoporosis and in 1997 for the prevention of osteoporosis. Osteoporosis is a disease characterized by bone loss and increased risk of bone fracture. There appears to have been several definitions of osteoporosis promulgated over time by different medical organizations, but an

individual traditionally is thought to have osteoporosis when his or her bone mineral density ("BMD") is more than 2.5 standard deviations below the mean for young adults of the same sex. This is referred to as a T-score of - 2.5. According to Dr. John Bilezikian, the chair of the Department of Endocrinology at Columbia University and Merck's retained expert witness at trial, osteoporosis afflicts ten to twelve million Americans and leads to roughly two million bone fractures every year. Another roughly thirty million Americans have low bone mass and are considered at risk of developing osteoporosis, a state which is referred to as osteopenia. Those with a T-score from - 1.5 to - 2.5 are thought to have osteopenia.

Since 2003, there have been various published reports of bisphosphonate users developing a rare condition called osteonecrosis of the jaw ("ONJ"). ONJ is characterized by an area of dead jaw bone that becomes exposed in the oral cavity. Symptoms can include pain, swelling, and purulent secretion.[1]

Plaintiff is a 72-year-old Florida resident who alleges that she developed ONJ as a result of taking Fosamax for nearly eight years. She filed a complaint against Merck on September 1, 2006 through her counsel, Timothy M. O'Brien, Esq., in the

[1] For additional information regarding Fosamax and the reported association between bisphosphonates and osteonecrosis of the jaw, see the Court's ruling on the parties' Daubert motions. In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009).

Northern District of Florida. The Judicial Panel on Multidistrict Litigation transferred the action to this Court on October 17, 2006, and it eventually became the first to go to trial of the roughly 800 actions that currently comprise this multidistrict litigation.

The first trial commenced on August 11, 2009, with Plaintiff asserting claims of strict liability and negligence rooted in theories of failure to warn and design defect, and fraudulent misrepresentation and concealment.[2] On September 1, 2009, after the close of evidence, the Court granted Merck's motion for judgment as a matter of law under Rule 50(a) on Plaintiff's fraudulent misrepresentation and concealment claims, finding that a reasonable jury could not find that Merck intentionally misrepresented or concealed the risk of ONJ before the date of Plaintiff's injury. Merck's motion for judgment as a matter of law was denied with respect to Plaintiff's other claims. After several days of deliberation, the jury informed the Court that it was deadlocked and could not reach a verdict on any of Plaintiff's claims. As a result, the Court declared a mistrial on September 11, 2009.

[2] In her Complaint, Plaintiff also brought claims for breach of express and implied warranties. Those claims were withdrawn by Plaintiff prior to the Court's order on Merck's motion for summary judgment.

Following the mistrial, Merck again moved for judgment as a matter of law under Rule 50(b). On March 26, 2010, the Court granted the motion in part, finding that Plaintiff had failed to establish proximate causation in that she did not introduce evidence from which a reasonable jury could conclude that Plaintiff's treating physician would not have prescribed her Fosamax even if he had been warned of the risk of ONJ. See In re Fosamax Prods. Liab. Litig., No. 06 Civ. 9455, 2010 WL 1257299, at *4-5 (S.D.N.Y. Mar. 26, 2010). The Court found, however, that Plaintiff had introduced sufficient evidence at trial to support her negligent design and strict liability design defect claims and thus denied Merck's motion with respect to those claims. See id. at *6-7.

The roughly three-week re-trial of Plaintiff's design defect claims began on June 7, 2010. Plaintiff was represented at trial by Mr. O'Brien and Gary Douglas, Esq. Mr. Douglas' involvement in the initial trial in August 2009 was limited to assisting Mr. O'Brien and his colleagues during jury selection. He had a more pronounced role in the re-trial, though, essentially splitting the questioning of witnesses with Mr. O'Brien and delivering an aggressive and impassioned closing argument.

The evidence introduced at the second trial was largely comparable to that in the first.

Plaintiff was prescribed Fosamax for the first time in July 1997 by Dr. James Mills, a board-certified obstetrician and gynecologist. At that time, Boles' hip T-score was - 2.1, meaning that she was osteopenic under current standards.[3]

According to Plaintiff's medical records, she began having jaw complications resembling an infection in August 2002 following a tooth extraction. Standard treatment methods including curettage and debridement were ineffective, and Plaintiff's condition persisted and gradually worsened. In late 2005, Plaintiff's medical records show that her condition deteriorated to the point where she had exposed necrotic bone in her jaw. She eventually developed three skin fistulas under her chin, which are small openings from which pus and other purulent liquids intermittently drain. Her condition has not subsided to date. Boles' long-time treating physician, Dr. James Elwell, told the jury that her pain has been at its worst for the past one and one-half to two years. He explained that the bone death extended into the area of her inferior alveolar nerve, which causes her increased pain and discomfort in the area of her lower lip, requiring treatment with narcotic pain medication.

[3] Plaintiff's medical records from that time reflect that her physician diagnosed her with osteoporosis using a then-accepted standard under which the threshold of the disease was a T-score of - 2.0. The exact diagnosis is irrelevant, however, because at all times Plaintiff took Fosamax it was indicated for use by patients with a T-score of - 2.0 or worse.

Because of her worsening condition, Dr. Elwell told the jury that he now recommends that Boles have resection surgery, a procedure during which the area of dead bone is surgically removed from the jaw and replaced with a metal plate.

Boles testified at trial that the pain she endures from her jaw condition is "hard to explain" and "sometimes [is] worse than others," but is like "sticking something sharp . . . . into [her] jaw" and it "radiates up the whole side of [her] face." (Trial Tr. at 1017.) She explained that she has a strong appetite, but her jaw condition has made it difficult for her to eat. She can still eat soft foods, but has lost about forty pounds since the onset of her condition. She also stated that if Dr. Elwell were to recommend that she have the resection surgery, she would comply. No date has been set for surgery.

Boles initially was diagnosed with a bone infection known as osteomyelitis. Dr. Elwell testified that based on her symptoms and unresponsiveness to traditional therapy, he since has been able to rule out all other possible causes and concluded that Plaintiff's use of Fosamax caused her to develop ONJ beginning in August 2002. He testified that he and Plaintiff's other treating physicians failed to diagnose Boles with ONJ in the early stages of her condition because at the time the medical community was unaware of the association between Fosamax and ONJ. Another of Plaintiff's treating

physicians, Dr. Patrick Anastasio, an infectious disease specialist, also opined that her condition is ONJ caused by her long-time Fosamax use.

Merck disputed Plaintiff's claim that she has ONJ, arguing that her jaw condition is osteomyelitis caused by severe periodontal disease and unrelated to her use of Fosamax. Merck argued that her condition has persisted because it had not been properly treated. Dr. Elwell acknowledged that Plaintiff has a bone infection, but believes she developed the infection and could not properly fight it off because of the pre-existing dead bone in her jaw caused by Fosamax. In essence, Merck argued that she has dead bone caused by an infection, whereas Plaintiff argued that she has an infection because of the dead bone in her jaw caused by Fosamax.

Along with the evidence that her jaw condition was caused by Fosamax, Plaintiff also sought to prove that the drug's benefits are minimal. According to Plaintiff's expert, Dr. Curt Furberg, the statistical studies of Fosamax conducted by Merck and reviewed by the FDA show that the drug has a definite fracture reduction efficacy, but only for a limited group of patients and for a limited period of time.

Dr. Furberg testified that, after reviewing the studies of Fosamax, he could find no evidence that Fosamax provides fracture reduction efficacy for users, like Plaintiff, who would

be considered osteopenic under most standards, that is individuals with no prevalent vertebral fracture and a T-score better than - 2.5. He focused on two reports which analyzed Merck's pivotal clinical trial referred to as the "Fracture Intervention Trial" or "FIT": an article published in the Journal of the American Medical Association ("JAMA"), and a report written by Dr. Anthony Mucci (the "Mucci Report"), a biostatistician for the FDA.

In the FIT trial, within the group of patients with a T-score of - 2.0 or worse, there were 22 percent less fractures in the group of patients receiving Fosamax than in the group receiving placebo. As such, as Merck often noted, the authors of the JAMA article provide that they "observed a 22% lower risk of clinical fracture in those whose T-scores were more than 2.0 [standard deviations] below the normal mean." (Pl. Ex. 2.0018.)

Dr. Furberg criticized the authors' conclusion, testifying that they needed to deconstruct the data further to arrive at an accurate conclusion. Looking at the data tables of the JAMA article, Dr. Furberg showed the jury that the group of patients in the study with a T-score worse than - 2.5 had a thirty-six percent fracture reduction benefit versus placebo. However, for the group of study patients with a T-score of - 2.5 to - 2.0, the data did not show a statistically significant benefit for Fosamax use compared to placebo: in fact, there were more

fractures in the group receiving Fosamax (92) than in the placebo group (87). Dr. Furberg believed that such "data pooling" was incomplete and misleading. He testified:

> This is a misleading way of presenting the findings. The benefit is, as we've seen in the [JAMA] analysis only in those who have a score of minus 2.5 or worse, and there's no benefit in the group between minus 2 and minus 2.5. So by combining them, it's misleading, you're combining a group with benefit with a group with no benefit, and scientifically, that doesn't make any sense. You don't do that. You don't combine groups with benefit with other groups where there's no benefit, and try to draw an overall conclusion. It's misleading. And I call it deceptive.

(Trial Tr. at 843.) Dr. Furberg read to the jury portions of the Mucci Report which showed that Dr. Mucci came to the same conclusion. In the report, Dr. Mucci concluded that "the nonosteoporotic cohort reveals no efficacy of Fosamax versus placebo for any category of fracture. . . . Thus, Fosamax can be said to be effective in osteoporotic patients with no prevalent vertebral fracture only if osteoporosis is defined in the more stringent fashion wherein the previous inclusionary criterion with BMD set as a negative 2 T-score is replaced by a new inclusionary criterion which sets BMD at a negative 2.5 T-score." (Id. at 757-58.) Even Merck's expert, Dr. Bilezikian, acknowledged the lack of solid evidence showing whether Fosamax provides fracture reduction benefit to that specific group of patients. See id. at 1496-97 ("Q. And in fact, your opinion is

that there is no evidence [of fracture benefit for the women who have a T-score of - 2.0 to - 2.5 with no prior vertebral fractures], but that doesn't mean it doesn't work. That's your opinion, right? A. Well, I think - - that's right. You need to do the study with the proper power before you can reach any conclusions.").

Dr. Furberg also analyzed for the jury the "life table graph" contained in the JAMA article, a line graph which compared the number of fractures sustained by Fosamax and placebo users during the four-year FIT trial. According to Dr. Furberg, the graph shows that the FIT study's Fosamax group sustained roughly the same number of fractures as the placebo group for the first eighteen months of the study. After eighteen months, the lines of the two groups diverge indicating that patients in the Fosamax group sustained fewer fractures, but then after thirty-six months of use, the instances of fracture within the two groups began to converge. These results indicate to Dr. Furberg that Fosamax is not efficacious for the first eighteen months of use and confers no added benefit after thirty-six months of use. Merck did not cross-examine Dr. Furberg on this timing issue and did not introduce any other studies to directly refute his conclusion.

Based on the foregoing evidence, Plaintiff argued to the jury that the risk of ONJ vastly outweighed the complete lack of

benefit to patients like Boles, who had a T-score better than - 2.5 and without a previous vertebral fracture. On June 25, 2010, after the thirteen-day trial, the jury found for Plaintiff on both her strict liability design defect and negligent design claims, awarding her $8 million in compensatory damages.

II. DISCUSSION

A. Motion for Judgment as a Matter of Law

Merck essentially raises two grounds for judgment as a matter of law. First, Merck argues that Plaintiff's negligent design and strict liability design defect claims fail because she provided no evidence from which the jury could have found for her on certain shared elements of those claims. Merck also argues these state law tort claims are preempted by federal law because the FDA effectively declared Fosamax safe and effective by approving it for sale for its indicated uses.

1. Rule 50 Standard

"Under Rule 50(a), a party may move for judgment as a matter of law during trial at any time prior to the submission of the case to the jury." Galdieri-Ambrosini v. Nat'l Realty & Dev. Corp., 136 F.3d 276, 286 (2d Cir. 1998); see Fed. R. Civ. P. 50(a). If the Court does not grant the Rule 50(a) motion at the close of evidence, the moving party may renew its motion for judgment as a matter of law under Rule 50(b) within 28 days of an unfavorable judgment, but it "is limited to those grounds

that were specifically raised in the prior [Rule 50(a) motion]." Galdieri-Ambrosini, 136 F.3d at 286; see Fed. R. Civ. P. 50(b).

The movant faces a "high bar," Lavin-McEleney v. Marist Coll., 239 F.3d 476, 479 (2d Cir. 2001); motions for judgment as a matter of law "should be granted cautiously and sparingly." Meloff v. N.Y. Life Ins. Co., 240 F.3d 138, 145 (2d Cir. 2001). In deciding the motion, the Court "must view the evidence in a light most favorable to the non-movant and grant that party every reasonable inference that the jury might have drawn in its favor." Merrill Lynch Interfunding, Inc. v. Argenti, 155 F.3d 113, 120-21 (2d Cir. 1998) (quoting Samuels v. Air Transport Local 504, 992 F.2d 12, 14 (2d Cir. 1993)). The Court "may not itself weigh the credibility of witnesses or consider the weight of the evidence." Galdieri-Ambrosini, 136 F.3d at 289. The Court may properly grant such a motion only where it "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for" the non-movant. Fed. R. Civ. P. 50(a); see Arlio v. Lively, 474 F.3d 46, 51 (2d Cir. 2007) (holding that judgment as a matter of law should be granted when "the evidence, viewed in the light most favorable to the nonmoving party, is insufficient to permit a reasonable juror to find in [the non-moving party's] favor").

2. Plaintiff Introduced Sufficient Evidence to Prevail at Trial

"Under Florida law, a strict product liability action based upon design defect requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury." Pinchinat v. Graco Children's Prods., Inc., 390 F. Supp. 2d 1141, 1148 (M.D. Fla. 2005). "[I]t is unnecessary in a strict liability action to show that the manufacturer has been negligent in any way. In fact [it] can be found liable even though [it] was utterly non-negligent." Moorman v. Am. Safety Equip., 594 So. 2d 795, 800 (Fla. Dist. Ct. App. 1992).

The basic elements of Plaintiff's negligence claim are well-established: "(1) a legal duty on the part of the defendant towards the plaintiff under the circumstances; (2) a breach of that duty by the defendant; (3) the defendant's breach of duty was both the actual and proximate cause of the plaintiff's injuries; and (4) the defendant suffered damages as a result of the breach." Pinchinat, 390 F. Supp. 2d at 1149. A plaintiff alleging negligent design also must show that the product was unreasonably dangerous. See Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003) (holding that a plaintiff alleging negligent design "also must establish that the product was defective or unreasonably dangerous"); Terex Corp. v. Bell,

689 So. 2d 1122, 1123 (Fla. Dist. Ct. App. 1997) ("Because the only evidence of negligence offered against appellant at trial related to its alleged negligent design and the jury found there was no design defect, there was no evidence to sustain its verdict.").

A product is unreasonably dangerous if "the risk of danger in the design outweighs the benefits."[4] Florida Standard Jury Instructions in Civil Cases § PL 5; see Martin v. JLG Indus., Inc., No. 8:06-CV-234, 2007 WL 2320593, at *3 (M.D. Fla. Aug. 10, 2007) ("A product can be found to be defectively designed if Plaintiff shows that the risk of danger in the design outweighs its benefits and that the design of the product proximately caused Plaintiff's injuries."); Sta-Rite Indus., Inc. v. Levey, 909 So. 2d 901, 904 (Fla. Dist. Ct. App. 2004) (applying the "risk-utility analysis").

[4] In certain circumstances Florida courts have held that a product alternatively could be found unreasonably dangerous under the "consumer expectation test," that is when plaintiff "demonstrate[s] that the product did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner." Force v. Ford Motor Corp., 879 So. 2d 103, 106 (Fla. Dist. Ct. App. 2004). The Court has repeatedly denied Plaintiff's requests to apply the consumer expectation test in this case because prescription pharmaceuticals are too complex for the straight-forward application of the consumer expectation test, and the Florida District Court of Appeals recently held broadly that it is an "inappropriate" test for determining defectiveness. See In re Fosamax, 2010 WL 1257299, at *6 n.4.

a. Risk Versus Benefit

Merck argues that it is entitled to judgment as a matter of law because Plaintiff did not establish that Fosamax is unreasonably dangerous in that its risks outweigh its benefits. After the first trial in this action, the Court rejected the same argument from Merck, finding that, based on the evidence introduced by Plaintiff, a reasonable jury could conclude "that the risks of Fosamax outweigh its benefits when used for the prevention of osteoporosis by those with a T-score better than -2.5." In re Fosamax, 2010 WL 1257299, at *6.

Essentially the same evidence is before the Court on this motion. The jury heard the testimony of Dr. Robert Marx, who opined that Fosamax generally can cause ONJ and discussed the effects of the condition. Boles and her treating physicians also testified regarding the effects of her condition and the pain that she has endured. Although Dr. Bilezikian testified regarding the seriousness of osteoporosis and the reasons for treating those with low bone mass, the jury was free to believe Dr. Furberg's opinion that there is no concrete scientific evidence that Fosamax prevents fractures in patients with a T-score better than - 2.5. Thus, as it did after the first trial, the Court finds that there was sufficient evidence from which a jury could conclude that Fosamax's risks outweigh its benefits,

or lack thereof, when used as indicated for the prevention of osteoporosis.

Merck argues, however, that such a finding is insufficient to sustain a jury verdict on Plaintiff's strict liability claim. It urges the Court to depart from its previous interpretation of Florida law and apply the Restatement (Third) of Torts: Products Liability § 6(c), which provides that a prescription drug is defectively designed only when "foreseeable risks of harm posed by the drug" are so high in comparison to the benefits that "reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients." Merck maintains that the "any class of patients" language means that Plaintiff must establish that Fosamax is defective for all potential users, and she cannot recover based on a theory that while Fosamax is not defective for one indicated use (treatment of osteoporosis), it is defective for the use for which she was prescribed (prevention of osteoporosis).

The Supreme Court of Florida has adopted the Restatement (Second) of Torts § 402A, see West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976), and Florida courts have consistently applied it since then. In a few instances Florida courts have cited approvingly to other sections of the Restatement (Third) regarding issues of product liability. See,

e.g., Warren ex rel. Brassell v. K-Mart Corp., 765 So. 2d 235, 237 (Fla. Dist. Ct. App. 2005) (citing § 2); Kohler Co. v. Marcotte, 907 So.2d 596, 598-99 (Fla. Dist. Ct. App. 2005) (citing §§ 2 and 5); Burch v. Sun State Ford, Inc., 864 So. 2d 466, 472 (Fla. Dist. Ct. App. 2004) (citing § 24). On the other hand, no Florida court has applied § 6 or the "any class of patients" language advanced by Merck, and others have explicitly declined to recognize the Restatement (Third). See McConnell v. Union Carbide Corp., 937 So. 2d 148, 151 n.4 (Fla. Dist. Ct. App. 2006) ("We purposefully forbear from any reliance on the Restatement (Third) of Torts and its risk-benefit analysis until the supreme court has recognized it as correctly stating the law of Florida."); cf. Tran v. Toyota Motor Corp., 420 F.3d 1310, 1312-14 (11th Cir. 2005) (reversing trial court for crafting a product liability jury charge from the Restatement (Third) rather than charging applicable Florida law as reflected in the Florida Standard Jury Instructions PL 5).

It must be remembered that a restatement is neither a statute nor a development of legislative code, but rather one organization's summary or opinion of certain principles of law. Courts are free to adopt certain sections as the law of their state and reject others. As a federal court sitting in diversity, the Court is hesitant to stitch into decades of Florida tort law one section of a treatise that its courts have

shown no apparent interest in adopting over the past twelve years. Therefore, the Court declines to apply the "any class of patients" standard advanced by Merck. Cf. Sobkowski v. Wyeth, Inc., No. 5:04-CV-96, 2004 WL 3569704, at *6 (M.D. Fla. May 17, 2004) (declining to allow plaintiff to assert liability under a Restatement theory "never before recognized under Florida law" because a federal court "is 'not free to engraft onto [state law] exceptions or modifications which may commend themselves to the federal court'" (quoting Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975))).

Even if the Court were to apply the "any class of patients" standard advanced in the Restatement (Third), Merck still would not be entitled to judgment as a matter of law. Dr. Furberg testified that Fosamax has not been shown to provide more than eighteen months of fracture reduction benefit across all patient groups. Merck did not cross-examine Dr. Furberg regarding this issue and did not call any witnesses or introduce any evidence to refute his conclusion. The jury was free to believe Dr. Furberg and agree with his conclusions, and thus it would be reasonable for it to find that the risk of ONJ outweighs this limited period of benefit for all users. For the foregoing reasons, Merck's argument on the issue of whether Fosamax is unreasonably dangerous lacks merit.

On a similar note, Merck contends that it is entitled to judgment as a matter of law under Florida's government rules defense. See Fla. Stat. Ann. § 768.1256. Under the statute, if the jury found that, at the time Fosamax was sold to Plaintiff "the aspect of the product that allegedly caused the harm" complied with all relevant FDA regulations, Merck would be entitled to a "rebuttable presumption" that Fosamax "is not defective or unreasonably dangerous".[5] Merck's argument here is entirely duplicative of its previous claim that Plaintiff failed to prove that Fosamax is unreasonably dangerous. The statute may entitle Defendant to a presumption provided that the jury found that it was in compliance with applicable FDA regulations, but it is not a complete bar against liability. To the extent that the jury believed Merck was entitled to a presumption, in

[5] The statute specifically provides: "In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm: (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury; (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product." Fla Stat. Ann. § 768.1256(1). Plaintiff is entitled to a contrary presumption if the fact-finder concludes that the manufacturer or seller was not in compliance with those same rules and regulations. Id. § 768.1256(2).

light of the aforementioned evidence introduced at trial from which a jury could reasonably conclude that Fosamax is unreasonably dangerous, it also could have found that the presumption was rebutted.

b. Foreseeability

Merck contends that it is entitled to judgment as a matter of law because there was no scientific evidence during the time Plaintiff used Fosamax from which it could have foreseen the risk of ONJ.[6]

With regard to Plaintiff's negligence claim, the foreseeability of ONJ bears on the issue of proximate causation. For Merck's failure to design a safe product to be a proximate cause of Plaintiff's injury, she must show that "prudent human foresight would lead one to expect that similar harm is likely to be substantially caused by the specific act or omission in question." McCain v. Fla. Power Corp., 593 So. 2d 500, 503 (Fla. 1992); Stazenski v. Tennant Co., 617 So. 2d 344, 346 (Fla. Dist.

[6] In its brief, Merck additionally argues that Plaintiff did not establish proximate causation on her negligent design claim. The basis of its argument is that Plaintiff was required but failed to show at trial that had Merck studied Fosamax further or implemented different safety surveillance, it would have resulted in different design for Fosamax and hence would not have caused her injury. In effect, Merck is arguing that the risk of ONJ was unforeseeable in that no matter how robust its safety review process, the risk of ONJ would not have been uncovered before it was used by Plaintiff. The Court considers this argument in conjunction with its argument on the issue of foreseeability.

Ct. App. 1993) ("In determining whether the action of the defendant is a proximate cause of the injury, the test is to what extent the defendant's conduct foreseeably and substantially caused the specific injury that actually occurred."). That burden is rather light in that Plaintiff need not show that the precise manner in which the injury occurred or the extent to which the injury was foreseeable. See Stazenski, 617 So. 2d at 347. "[A]ll that is necessary in order for liability to arise is that the tortfeasor be able to foresee that some injury will likely result in some manner as a consequence of his negligent acts." Crislip v. Holland, 401 So. 2d 1115, 1117 (Fla. Dist. Ct. App. 1981). The proximate cause inquiry typically is an issue of fact for the jury, one that can be decided as a matter of law only "where evidence supports no more than a single reasonable inference." McCain, 593 So. 2d at 504; Palma v. BP Prods. N. Am., Inc., 594 F. Supp. 2d 1306, 1310-11 (S.D. Fla. 2009); see also Lindsey v. Bell South Telecomms., Inc., 943 So. 2d 963, 966 (Fla. Dist. Ct. App. 2006) ("The circumstances under which a court may resolve proximate cause as a matter of law are extremely limited.").

Merck also points to Florida's state of the art defense, which provides that the finder of fact in a design defect case "shall consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of

manufacture, not at the time of loss or injury." Fla. Stat. Ann. § 768.1257; see also Levey, 909 So. 2d at 904 (finding strict liability claim supported by the evidence because of the "reasonable foreseeability" of the manner the product caused plaintiff's injury). Merck construes the statute to mean that in order for Plaintiff to prove that Fosamax was unreasonably dangerous, she has the burden of introducing evidence to show that the risk of ONJ was foreseeable at the time of her injury. Florida law on this point is not particularly clear. Regardless, even if Merck is correct that the issue of foreseeability also bears on whether the product is unreasonably dangerous, that burden cannot be any weightier than that which applies to her negligent design claim. Plaintiff has met that burden.

There are two types of tissue that comprise human bones: cancellous bone and cortical bone. It was not disputed by Merck that the mandible is made up of cancellous bone, which attracts more bisphosphonate than cortical bone and thus causes a higher suppression of bone turnover in the area. Histomorphomertic studies have shown Fosamax to suppress bone turnover in patients by 94%, and by 98% when combined with estrogen therapy. FDA officers reviewing these studies wrote that the 98% reduction in bone turnover is "of concern" and the "almost total lack of mineralizing surface is frightening". (Trial Tr. at 1180-86.)

Simply because Plaintiff could not point to a scientist who explicitly predicted before 2003 that the severe suppression of bone turnover caused by Fosamax could lead to ONJ, does not necessarily mean that it was not foreseeable. Merck's own employee, Dr. Donald Kimmel, a bone biologist, theorized that Fosamax's effect of drastically reducing bone turnover could reduce the jaw's ability to heal when threatened by challenges such as poor dental health. He wrote in a 2006 email: "[W]hen the bone is fully healthy and called upon to fight chronic untreated periodontitis, we know that it eventually loses in most patients. It just takes a long time, like until age 80-85 sometimes. If its ability to remodel and do everything it is capable of doing is impaired, as it would be by bisphosphonate treatment, it makes sense to me to think that it should lose the battle sooner and more convincingly." (Kimmel Dep. at 319-20.)[7] Dr. Kimmel acknowledged that Merck and the rest of the scientific community knew all of the requisite information, including the extent to which Fosamax suppresses bone turnover, necessary to make this connection between Fosamax and ONJ before Fosamax was released to the market.

Plaintiff also introduced several adverse event reports received by Merck prior to the onset of Plaintiff's injury that

[7] All depositions referenced in this Opinion and Order were videotaped and played for the jury during trial.

detail dental and jaw complications experienced by Fosamax users. None use the term ONJ or osteonecrosis of the jaw, but many describe symptoms associated with the condition. Merck focuses on the fact that none of Plaintiff's expert witnesses testified that the risk of ONJ was foreseeable based on the adverse event reports in the company's possession prior to Plaintiff's injury, but ignores the fact that Dr. Michael Goldberg, Merck's former director of clinical risk management and safety, conceded that at least one of the reports could have been a case of ONJ. (Goldberg Dep. at 445-46.)

In addition, a 1981 study published in the Journal of Periodontal Research found that high doses of clodronate, a first-generation bisphosphonate, induced ONJ in rice rats with periodontal disease. Certainly a study involving rats rather than humans ingesting a bisphosphonate other than Fosamax has its shortcomings. As the Court previously held, by itself, this animal study "would not provide enough support for the conclusion that Fosamax can cause ONJ." In re Fosamax, 645 F. Supp. 2d. at 187. Nonetheless, it is evidence from which a jury could conclude that Merck could have foreseen that the suppression of bone turnover associated with Fosamax could lead to jaw bone death.

Confronted with the foregoing evidence, a jury could have concluded that the risk of ONJ was reasonably foreseeable.

2. Plaintiff's Claims are not Preempted by Federal Law

Merck contends that it is entitled to judgment as a matter of law because the state tort law under which Plaintiff's claims arise is preempted by federal law. It specifically argues that "the FDA has determined, applying federal law, that Fosamax can be on the market and used for its indicated purposes because it is safe and effective, and Plaintiff seeks to use state tort law to contradict that finding." (Def. Br. at 25.)

The Supremacy Clause of the United States Constitution dictates that "state and local laws that conflict with federal law are 'without effect.'" N.Y. SMSA Ltd. P'ship v. Town of Clarkstown, 612 F.3d 97, 103-04 (2d Cir. 2010) (quoting Altria Group, Inc. v. Good, --- U.S. ---, 129 S. Ct. 538, 543, 172 L. Ed. 2d 398 (2008)). Courts generally have recognized three scenarios in which federal law preempts state or local law: "(1) where Congress expressly states its intent to preempt; (2) where Congress's scheme of federal regulation is sufficiently comprehensive to give rise to a reasonable inference it leaves no room for the state to act; and (3) where state law actually conflicts with federal law." Marsh v. Rosenbloom, 499 F.3d 165, 177 (2d Cir. 2007). At issue here is the third instance, conflict preemption, which occurs when (1) "compliance with both state and federal law is impossible," or (2) "when the state law stands as an obstacle to the accomplishment and execution of the

full purposes and objectives of Congress." California v. ARC America Corp., 490 U.S. 93, 100-101 (1989) (quotation omitted); see SPGGC, LLC v. Blumenthal, 505 F.3d 183, 188 (2d Cir. 2007).

Every preemption inquiry begins by determining the intent of Congress. See Medtronic v. Lohr, 518 U.S. 470, 485-86 (1996) (recognizing that every preemption case is guided by the "oft-repeated comment" that "the purpose of Congress is the ultimate touchstone"). "In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Wyeth v. Levine, --- U.S. ---, 129 S. Ct. 1187, 1194-95, 173 L. Ed. 2d 51 (2009) (quoting Medtronic, 518 U.S. at 585 (modifications omitted)); see Wachovia Bank, N.A. v. Burke, 414 F.3d 305, 314 (2d Cir. 2005) ("There is typically a presumption against preemption in areas of regulation that are traditionally allocated to states and are of particular local concern."). Plaintiff benefits from the presumption here because states traditionally have regulated matters of health and safety and, as the Supreme Court has repeatedly held, "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of

action.'" Levine, 129 S. Ct. at 1195 n.3 (quoting Medtronic, 518 U.S. at 485); see also Desiano v. Warner-Lambert & Co., 467 F.3d 85, 94 (2d Cir. 2005) (recognizing that "state-based tort liability falls squarely within [a state's] prerogative to regulate matters of health and safety, which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest" (quotation and modification omitted)).

Merck does not articulate how it is impossible for it to comply with both Florida tort law and FDA regulations. The ultimate goal of each is to protect patients by ensuring that the drugs on the market are both safe and effective for their indicated use. Aside from the obligations imposed by the FDA on drug manufacturers seeking market approval, the Florida law at issue here imposes an additional duty of care on manufacturers in designing those drugs and holds them strictly liable to the extent a defective product reaches the market. Perhaps, in some rare instance, a state duty could require that "the manufacturer do something that the FDA forbade or vice versa," but that is not the case here. Wimbush v. Wyeth, No. 09-3380, 2010 WL 3256029, at *9 (6th Cir. Aug. 18, 2010); cf. Colon ex rel. Molina v. BIC USA, Inc., 136 F. Supp. 2d 196, 207 (S.D.N.Y. 2000) ("If the requirements for the design . . . of a disposable lighter set by state common law provide a higher degree of protection than the federal standard . . . it would not

necessarily mean a conflict exists, although it may mean that in order for manufacturers to protect themselves from liability they may have to design . . . disposable lighters in compliance with the higher standard established by the courts.").

Neither is the Court persuaded that Florida tort law stands as an obstacle to the FDA's role in determining which drugs are safe and effective. A similar claim already has been rejected by the Supreme Court in Levine, in which a drug manufacturer found liable for a failure to warn under state tort law argued on appeal that the state law obstructed the purposes and objectives of federal drug labeling regulation. The appellant in Levine employed similar logic to that of Merck here, that is, once the FDA approved a drug's label, a state-law verdict may not trump the agency's conclusion and deem that label inadequate. In rejecting that argument, the Court reasoned that Congress's failure to enact an express preemption provision in the Federal Food Drug and Cosmetic Act with regard to prescription drugs,[8] "coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Levine, 129 S. Ct.

[8] "Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices." Riegel v. Medtronic, Inc., 552 U.S. 312, 327 (2008).

at 1200; see also Desiano, 467 F.3d at 95 ("[W]ere we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result."). The Court viewed state tort law not as an obstacle, but as "a complementary form of drug regulation." Levine, 129 S. Ct. at 1202; cf. Wimbush, 2010 WL 3256029, at *10 ("Simply because tort liability 'parallel[s] federal safety requirements' does not mean that liability is preempted." (quoting Desiano, 467 F.3d at 95)). As with the state duty to warn at issue in Levine, the duty to design a safe and effective product serves the same complementary role: to "uncover unknown drug hazards," to "provide incentives for drug manufacturers to disclose safety risks promptly," and to "serve a distinct compensatory function that may motivate injured persons to come forward with information." Levine, 129 S. Ct. at 1202.

The Supreme Court's analysis in Levine is equally applicable to this case. Florida tort law is not an obstacle to FDA regulation, but serves a complementary role. Thus, Plaintiff's claims are not preempted by federal law.

B. Motion for a New Trial

1. Rule 59 Standard

Following a jury trial, Rule 59(a)(1)(A) provides a court discretion to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." In considering a motion under Rule 59, the court "is free to weigh the evidence . . . and need not view it in the light most favorable to the verdict winner." DLC Mgmt. Corp. v. Town of Hyde Park, 163 F.3d 124, 134 (2d Cir. 1998). The motion may be granted "even when there is evidence to support the jury's verdict, so long as the court 'determines that, in its independent judgment, the jury has reached a seriously erroneous result or its verdict is a miscarriage of justice.'" AMW Materials Testing, Inc. v. Town of Babylon, 584 F.3d 436, 456 (2d Cir. 2009) (quoting Nimely v. City of New York, 414 F.3d 381, 392 (2d Cir. 2005)).

Where, as here, the motion for a new trial is based on the alleged misconduct of trial counsel, the court must consider such a claim "in the context of the trial as a whole, examining, among other things, the 'totality of the circumstances, including the nature of the comments, their frequency, their possible relevancy to the real issues before the jury, and the manner in which the parties and the court treated the comments.'" Okraynets v. Metro. Transp. Auth., 555 F. Supp. 2d

420, 429 (S.D.N.Y. 2008) (quoting Hynes v. LaBoy, 887 F. Supp. 618, 632 (S.D.N.Y. 1995) (modifications omitted)). "Trial courts possess broad discretion to determine when the conduct of counsel is so improper as to warrant a new trial." Matthews v. CTI Container Transp. Int'l Inc., 871 F.2d 270, 278 (2d Cir. 1989); Johnson v. Celotex Corp., 899 F.2d 1281, 1289 (2d. Cir. 1990) ("[T]he judge who was present throughout the trial [is] best able to determine the effect of the conduct of counsel on the jury."). "Obviously not all misconduct of counsel taints a verdict to such a degree as to warrant a new trial." Pappas v. Middle Earth Condo. Ass'n, 963 F.2d 534, 540 (2d Cir. 1992). Only "when the conduct of counsel in argument causes prejudice to the opposing party and unfairly influences a jury's verdict" is a new trial warranted. Id.; see also Strobl v. N.Y. Mercantile Exch., 582 F. Supp. 770, 780 (S.D.N.Y. 1984) ("In ruling on a motion for a new trial based on attorney misconduct, the trial court must determine whether counsel's conduct created undue prejudice or passion which played upon the sympathy of the jury.").

In certain circumstances a court may choose to order a remittitur in lieu of a new trial. "Remittitur is the process by which a court compels a plaintiff to choose between reduction of an excessive verdict and a new trial." Cross v. New York City Transit Auth., 417 F.3d 241, 258 (2d Cir. 2005). Even where, as

here, "the non-prevailing party has not formally moved for remittitur, a court may, sua sponte, offer the prevailing party the remittitur as an alternative to a new trial." United States ex rel. Maris Equip. Co. v. Morganti, Inc., 163 F. Supp. 2d 174, 191 (E.D.N.Y. 2001). The Court of Appeals has

> found remittitur appropriate in at least two distinct kinds of cases: (1) where the court can identify an error that caused the jury to include in the verdict a quantifiable amount that should be stricken, and (2) more generally, where the award is 'intrinsically excessive' in the sense of being greater than the amount a reasonable jury could have awarded, although the surplus cannot be ascribed to a particular, quantifiable error.

Trademark Research Corp v. Maxwell Online, Inc., 995 F.2d 326, 337 (2d Cir. 1993) (quotation and modification omitted). A remittitur is inappropriate, however, where "the record establishes that the jury's verdict on damages was not only excessive but was also infected by fundamental error." Ramirez v. New York City Off-Track Betting Corp., 112 F.3d 38, 40 (2d Cir. 1997). In such an instance, the appropriate remedy is a new trial on damages. Id.; Uddin v. New York City Admin. for Children's Servs., No. 99 Civ. 5843, 2001 WL 1512588, at *5 (S.D.N.Y. Nov. 28, 2001) ("Where the trial record establishes that the jury's verdict on damages was 'infected by fundamental error,' the judgment should be vacated in favor of a new trial on damages." (quoting Ramirez)).

2. Counsel's Conduct at Trial

Merck's motion for a new trial is based entirely on the behavior of Plaintiff's counsel during trial. Mr. O'Brien and Mr. Douglas split the trial duties, with Mr. O'Brien handling the opening statement and most witnesses, and Mr. Douglas examining others and delivering the Plaintiff's summation.

The Court acknowledges at the outset that Mr. Douglas' behavior at trial fell far shy of the standards for professional conduct to which members of the bar in this district are expected to conform. The misconduct was not as widespread as Merck suggests in its motion, however. Counsel for Merck knows as well as the Court that the instant motion for a new trial was brought about by the manner in which Mr. Douglas treated Merck's expert witness on cross-examination and the theatrics and hyperbole he employed in summation. The Court first addresses Merck's complaints regarding Plaintiff's opening statement and case in chief, then moves to the core aspect of inappropriate behavior at trial: the disparaging and insulting manner in which Mr. Douglas treated defense witnesses and his outrageous behavior and accusations in summation.

a. Opening Statement and Plaintiff's Case

Merck's complaints regarding Mr. O'Brien's opening statement and Mr. Douglas' tactics during direct examination are manufactured in hindsight and detract from the core issues.

For example, counsel's comments regarding the information available to Plaintiff's treating physicians was not improper. During his opening statement at the re-trial, Mr. O'Brien claimed that "oral surgeons in this timeframe, 2002 and 2003, and the years before, are left to figure it out on their own. Without any help, without any instruction, without any information at all from Merck about these jaw problems in their files that they were sharing with no one."[9] (Trial Tr. at 96.) Merck describes these isolated comments as "a campaign to introduce and highlight the issue of failure-to-warn" after that claim already had been dismissed. (Def. Br. at 6.) In the Court's view, the statements highlighted by Merck were fair argument on the issue of causation. Plaintiff's treating physician did not initially diagnose her jaw condition as ONJ – a fact that Merck repeatedly dwelled on at trial in arguing that Plaintiff did not have ONJ – and therefore it is not improper for counsel to argue that the reason for Plaintiff's treating physician's initial diagnosis was a lack of information regarding the association between bisphosphonates and ONJ. It also was fair for counsel to note that Merck in fact had such

[9] Similarly, during summation, Mr. Douglas referenced the fact that Merck had information regarding ONJ that was unavailable to the public: "She had a history of dental problems. She went on Fosamax. They knew it [in] 2004. While Dr. Elwell was scratching his head, why won't she respond to therapy?" (Trial Tr. at 1704.)

information to counter the argument that the risk of ONJ was unforeseeable.

In addition, Merck's argument that Mr. O'Brien attempted to generate regional sympathy for Plaintiff during his opening statement based on the recent oil spill in the Gulf of Mexico is contrived and without merit. The Court itself, during voir dire, introduced Plaintiff as hailing from the "panhandle of Florida," the area "which sadly may be affected by that awful oil spill." (Trial Tr. at 11.) On the other hand, in describing Plaintiff's medical history, counsel obliquely stated: "[T]he very first tooth extraction that occurred after Ms. Boles had been on Fosamax [a] catastrophe broke out in her mouth, and it's been spilling over ever since." (Id. at 116.) Describing Plaintiff's medical condition in that manner was not improper. Not once did counsel utter the words "oil" or "BP" to the jury during his opening statement or any other part of the trial. To the extent counsel's description of Plaintiff's injury "spilling over" was a passive attempt to generate regional sympathy from the jury – a jury comprised of individuals from counties comprising the Southern District of New York – it was an attempt that was lost on the Court and incapable of resulting in prejudice against Merck.

Merck's argument that Mr. Douglas ignored court orders in direct examination of witnesses is also overblown. Mr. Douglas

generally questioned witnesses on direct examination within the bounds set by the Court's rulings on evidentiary motions and contemporaneous objections. Counsel's passing reference to another bellwether case in this multidistrict litigation was in violation of clear instructions by the Court,[10] but its impact on the jury was de minimis. At most the jury learned that another individual sued Merck; counsel did not discuss the underlying allegations of the action, and it was only mentioned once over the span of the thirteen-day proceeding. Assuming the comment registered with the jury, its knowledge of a single additional Fosamax-related lawsuit is not so prejudicial as to require a new trial. Even if, as Merck suggests, this limited exchange invited members of the jury to conduct independent research about the magnitude of this litigation despite the Court's repeated instructions not to do so, what the jury would have

[10] During the first trial, the Court repeatedly warned counsel that the jury should not be made aware of the fact that Plaintiff's claim is but one of hundreds comprising this multidistrict litigation. As the Court then explained, the case "involves one plaintiff and one defendant" and so the "jury has no business knowing whether there's an MDL" because "the fact there are a lot of other cases brought could very understandably inure to the detriment of the defendant." (Aug. 13, 2009 Tr. at 273-274.) At the outset of the re-trial, the Court warned the parties that in the event one wished to impeach a witness with an inconsistent statement, counsel should refer to such testimony as "another proceeding" or "other testimony" because the jury need not know that the case previously resulted in a mistrial. Despite these warnings, counsel directed a witness' attention to a transcript by questioning whether she had been asked "questions about some testimony you gave in a case called Maley v. Merck here on April 20." (Trial Tr. at 984.)

found is that the only other Fosamax-related action to go to verdict resulted in a defense judgment.

b. Cross-Examination and Plaintiff's Summation

To put it kindly, Mr. Douglas' style of advocacy was aggressive and boisterous. In Merck's words, it was a vaudeville – a conscious campaign "to manipulate the evidence and the jury, to belittle Merck and its witnesses, and to distract the jury." (Def. Br. at 1.) Although a court reporter may not be able to fully capture the alleged farce in a written record, Mr. Douglas' periodically outlandish behavior at trial remains fresh in the mind of the Court.

Counsel's rude treatment of defense witness began with the cross-examination of Dr. Robert Glickman, Merck's retained expert on the issue of specific causation. Before counsel even asked a question regarding ONJ or Plaintiff, counsel provoked Dr. Glickman with sarcasm, mockery, and condescending questions. For example, after Dr. Glickman explained why he did not understand the pending question posed by Mr. Douglas, he responded: "Would you like a glass of water? Are you okay? Slow down. Not a trick question. I just want to ask you whether you did a report or not. Something wrong with that?" (Trial Tr. at 1360.) Although in that instance and others, counsel's words during cross-examination could be read as polite from the record, they were conveyed with scorn and derision.

Counsel later accused Dr. Glickman of being defensive — an observation that was correct in light of the offensive manner in which counsel was conducting himself, but nonetheless an accusation that is improper to make before the jury. Dr. Glickman was not exactly forthcoming on cross-examination, but there are a multitude of proper methods that can be used to control a difficult witness on cross-examination that are not offensive and rude.

The Court admonished counsel outside the presence of the jury for the manner in which he cross-examined Dr. Glickman,[11] but apparently the warning fell on deaf ears. Counsel's theatrics were only amplified in his closing argument. Mr. Douglas delivered his argument in an agitated tone, scuttling about the well of the courtroom, oddly gesturing, singing, and laughing, a style that may best be described as manic. With a gallery full of faces unfamiliar to the Court but all seemingly familiar to Mr. Douglas, he created a sideshow of conspiracy theories, jokes at the expense of defense witnesses, and was admittedly "fooling around" and "making fun." (Id. at 1672.) The Court is mindful that wit and sarcasm are often useful tools for

[11] The Court warned counsel that "[t]his isn't Law and Order, and in my generation, it's not Perry Mason" so "put [on] your questions . . . stop the sarcasm" and "don't be a wise guy." (Tr. at 1394.). The Court also called Mr. O'Brien to the sidebar on another occasion and told him off the record that Mr. Douglas should stop acting unprofessionally.

trial lawyers, but Mr. Douglas' use of such methods crossed the line between zealous advocacy and inappropriate behavior.

For example, Mr. Douglas returned to his favorite target, Dr. Glickman, the so-called "guy who knows nothing about bisphosphonate-related ONJ." (Id. at 1672.) Rather than solely focusing on the substance of the expert's testimony, Mr. Douglas made fun of the manner in which it was conveyed, referring to Dr. Glickman's use of slides during direct testimony as "a dog and pony show" in which he "read[] from the board" using "his fancy flashcards," and telling the jury that he would "bet dollars to doughnuts that Dr. Glickman didn't read those medical records." (Id. at 1671-72.) Counsel also mocked the testimony of Dr. Anne de Papp, a Merck doctor, who during direct examination commented as an aside that she recently had observed an elderly woman on the local commuter train who she believed suffered from severe osteoporosis based on the woman's hunched posture. Counsel felt it necessary to attack that insignificant background testimony in summation: "But she can diagnose fractures riding the subway. Is it the A train? Or is it the number 4 train? Is it going uptown? Or is it going downtown? Is it in Russia? Do you have to have your coat on? Don't you have to take your coat off?" (Id. at 1688.)

Mr. Douglas' head-scratching attempts at humor were not limited to criticizing defense witnesses. He felt it necessary

to comment on opposing counsel's initial failure to address him by name, stating: "I appreciate Mr. Strain eventually started to refer to me by name and I appreciate that, as opposed to 'the lawyer,' not to be confused with 'the chair' or this table, but, you know, that's just stuff, techniques that lawyers use, you know, dehumanize the other side, easier to turn that, whatever it is, it's his business, whatever." (Id. at 1677.) Mr. Douglas also presented to the jury a demonstrative containing the single word "hypocrisy" in oversized bold capital letters, a superfluous visual aid for his slant on the conduct of Merck and defense counsel. His most gratuitous gag involved an illustration of a ship falling off the edge of the world, which he used to compare Merck's hesitance to recognize the relationship between Fosamax and ONJ as synonymous to membership in the "Flat Earth Society."

Merck complains that Mr. Douglas focused on secondary aspects of the case in a calculated attempt to inflame the jury. He likened the FDA's ability to regulate drugs to the Government's shortcomings in responding to the damage caused by Hurricane Katrina. He also construed limited testimony from Plaintiff's regulatory expert regarding industry funding to condemn the FDA's objectivity, characterizing the agency as having an "incestuous" relationship with pharmaceutical companies under which it gives cursory reviews and expedited

approvals of new drug applications "in exchange" for funding (Id. at 1680-82.)

When Mr. Douglas managed to stay on topic and review the core evidence in the case, he did not always portray it fairly.[12] Merck complains of a slide used by Mr. Douglas during closing argument which summarized an adverse event report from 1999 that described a dental condition called exostosis experienced by a Fosamax user. When Dr. Michael Goldberg, a Merck employee, testified about this report during his deposition in 2008, he stated that based on what he knew at that time, what was described in the report in 1999 "could be ONJ." (Goldberg Dep. at 445-46.) Despite the fact there was no testimony from Dr. Kimmel regarding this report, Plaintiff's slide read "Merck's Dr. Kimmel and Dr. Goldberg Both Called [the Report] ONJ from 1999." (Beausoleil Decl., Ex. 3.) The error was limited to the slide. Although Mr. Douglas asked his assistant to call up the "Dr. Goldberg and Dr. Kimmel both call it ONJ" slide, he described the substance of the report fairly.

[12] Merck argues that Mr. Douglas misstated the date of the Mucci Report by suggesting that the report post-dated the FDA's review and approval of the FIT study. See Trial Tr. at 1697 ("This is what Mucci discovered later on when you break it down. Holy Moly. Now it's too late. It's on the market."). The Court initially agreed with Merck, but upon a closer inspection of the record, it appears that Mr. Douglas' comments were proper. Dr. Mucci's report post-dated the FDA's approval of Fosamax in 1997 for the prevention of osteoporosis.

In dismissing claims for punitive damages, the Court previously held that no jury could reasonably find that Merck's "actions rose to the level of intentional misconduct." Nevertheless, Mr. Douglas created a baseless conspiracy theory to the effect that Merck knew that Fosamax provides no benefit to osteopenic users, but sought to convince that class of patients that treatment was necessary in order to sell more pills and, in turn, make more money. In Mr. Douglas' words:

> "[N]o matter how you want to pool data, no matter how you want to spin things to the FDA, no matter how you want to spend money on organizations to define criteria for treatment as low as possible so you can sell more pills, and that's what's going on here. Let's give Fosamax to everyone in the world. And I'm not surprised. . . . They sell it for profit. They sell those pills, and it is clearly . . . their goal, and I'm going to talk about that, their goal is to sell more pills. To convince folks like Mrs. Boles, to convince folks that they should be frightened that unless you take this pill you're going to die. . . . Whoo, everybody better get Fosamax.

(Trial Tr. at 1663-64.)

Mr. Douglas vilified Dr. Bilezikian as an extension of this plan. On direct examination, Dr. Bilezikian explained to the jury the risks of osteoporosis and detailed his efforts to teach physicians how to diagnose and treat the disease. He showed the jury a diagram containing a traffic light that he uses regularly in his teaching as a visual aid to depict the groups of patients that carry the highest risk of sustaining a fracture and the prudent course of treatment within each group to minimize

fracture risk. On cross-examination, Dr. Bilezikian acknowledged that he has a longstanding professional relationship with Merck and other drug companies in that roughly twenty percent of his income for the past ten years is derived from consulting work for drug companies. Mr. Douglas seized on that testimony to simultaneously mock Dr. Bilezikian's teaching aids and tie him into this conspiracy to scare people into believing that they will die from osteoporosis unless they take Fosamax. Mr. Douglas called Dr. Bilezikian an "industry mouthpiece" that "travels the world" as part of "a dog and pony show" to "sell more pills." (Id. at 1682-83.) He theorized that Dr. Bilezikian could benefit from a "theme song," singing: "Fosamax, Fosamax, every day. Take one every day and keep your brittle bones away." (Id. at 1683.). He later spouted: "Dr. Bilezikian . . . scared people into thinking everybody is at risk and came in and gave - - with the traffic light thing, told you there's 300 hip fractures a year. 30 percent of those people will die. Die? Really? Or worse. Worse? What's worse than death? They may end up in a nursing home. Nursing home, no. A nursing home? A nursing home. That's worse than death. Where can I get some more of that Fosamax?" (Id. at 1690-91.)

The argument that Merck intentionally misrepresented Fosamax's benefits to increase profits appeared to be an attempt to put the issue of punitive damages before the jury. Further

supporting that conclusion is the fact that Mr. Douglas asked the jury to return a verdict that would "say something to Merck." (Id. at 1710.) Mr. Douglas stated again during his discussion of damages: "We have this courthouse because of things like this where you can set it right, and you have the power to say this in your verdict, to say to Merck, 'No.'" (Id. at 1711.)

Immediately after the jury left the courtroom, the Court commented that it was "clear that what was being said was an effort to inject punitive damages into the case, which was clearly improper." (Id. at 1713.) At the request of Merck, the Court instructed the jury the next morning during its charge of law that a damage calculation should be purely compensatory:

> One final word about damages. During yesterday's summation, plaintiff's counsel urged, Mr. Douglas urged you to render a damages verdict that would "say something to Merck." In other words, Plaintiff's counsel urged you to render a verdict that would punish Merck. Plaintiff's counsel's argument was inconsistent with the law. If you decide to render a damages verdict for Plaintiff, that verdict should not be aimed at punishing Merck or "sending a message" to Merck or anybody else. The purpose of any damages you may render should be solely to compensate Plaintiff for her injury.

(Id. at 1738-39.)

C. A New Trial is Not Warranted

The Court in no way condones the Mr. Douglas' "outrageous" conduct at trial. Nevertheless, viewing Mr. Douglas' behavior

in the context of the trial as a whole, a new trial is not warranted. As the Court described above in denying Merck's Rule 50 motion, Plaintiff introduced sufficient evidence to sustain a verdict. Although the Court disapproves of the manner in which Mr. Douglas delivered his summation, it cannot conclude that his unusual antics prejudiced Merck. The majority of questionable conduct raised by Merck and noted by the Court did not touch on the key evidence of the case. No matter how much counsel criticized the FDA's ability to regulate drugs or mocked the defense witnesses' courtroom demeanor, those comments had little impact on the fundamental questions the jury was called upon to answer, that is, whether the evidence showed that Fosamax's risks outweigh its benefits and whether the drug caused Plaintiff to develop ONJ. Moreover, it did not take a trained lawyer to realize that Mr. Douglas was acting unprofessionally and treating Merck's witnesses unfairly. Following the performance of a Dr. Bilezikian theme-song, "Flat-Earth Society" illustrations, and often unintelligible rambling, it would seem difficult to take him seriously when he calmed down and actually discussed the central issues of the case. Mr. Douglas' conduct easily could have inured to the detriment of his client, and only with hindsight does it appear to an outsider that his outlandish behavior led to a verdict for the Plaintiff.

The alleged mischaracterizations of the evidence in Mr. Douglas' summation raised by Merck were de minimis considering the scores of scientific evidence introduced over the span of the three-week trial. The slide which mentioned Dr. Kimmel was viewable only for a few moments. Even assuming the jury read the details of the slide, Mr. Douglas verbally described the evidence accurately, minimizing any prejudice. Moreover, the Court repeatedly instructed the jury that an attorney's statements are not evidence and it is their own recollection of the evidence that controls. Just as Merck and the Court recalled that Dr. Kimmel did not testify in that manner, the jury likely remembered as well.

The Court was of the opinion at trial that counsel's comments regarding Merck's campaign to "sell more pills" and his call for the jury to "say something to Merck" was a roundabout attempt to put the issue of punitive damages before the jury. The Court is mindful that the Court of Appeals previously has found unpersuasive the argument for a new trial that an attorney "injected bias into the proceedings by asking the jury to 'send a message' with its damage award," finding the comment "totally appropriate." Ramirez, 112 F.3d at 40. Mr. Douglas, however, went beyond merely suggesting that the jury "send a message" to Merck; he also argued that Merck intentionally misrepresented the effectiveness of its product for monetary gain. Despite

Ramirez, the Court is still of the opinion that Mr. Douglas intended to inject into the trial the issue of punitive damages.

For that reason, after summation, the Court amended its jury charge to include a rather strongly-worded instruction that specifically stated that Mr. Douglas' statements were contrary to law and that, in the event it thought damages were warranted, it should arrive at the figure which would fairly compensate Plaintiff for her injury. The Court is confident that any prejudice resulting from Mr. Douglas' summation was dispelled by the curative instruction. See CSX Transp., Inc. v. Hensley, --- U.S. ---, 129 S. Ct. 2139, 2141, 173 L. Ed. 2d 1184 (2009) ("The jury system is premised on the idea that rationality and careful regard for the court's instructions will confine and exclude jurors' raw emotions. . . . [J]uries are presumed to follow the court's instructions."); United States v. Whitten, 610 F.3d 168, 191 (2d Cir. 2010) ("We presume that juries follow instructions . . . .").

Merck points to the size of the damage verdict and the fact that it surpassed by $3 million the amount suggested by counsel as evidence that the Court's instruction on damages was disregarded and the verdict was punitive in nature. See Whittenburg v. Werner Enter., Inc., 561 F.3d 1122, 1132 (10th Cir. 2009) ("[T]he size of a verdict — whether it is large or excessive — is a significant factor suggesting prejudice

sufficient to require a new trial."). The verdict was unreasonably high, but the Court is not convinced that the large verdict was a result of counsel's summation. The jury is not bound to reach a damage verdict at or below the amount suggested by Plaintiff's counsel. Considering that the curative instruction regarding punitive damages was pointed and timely, the $8 million verdict is more likely explained by a jury out of touch with the amount of money that would reasonably compensate Plaintiff for her injuries, than a jury seeking to punish Merck.

For the foregoing reasons, the Court does not believe that Mr. Douglas' behavior at trial prejudiced Merck to a sufficient degree as to warrant a new trial under Rule 59.

D. Remittitur is the Appropriate Remedy

As noted above, the Court believes the $8 million verdict is unreasonably high, but cannot point definitively to anything in the record that caused the surplus. In such an instance, remittitur is appropriate.

In considering a remittitur in a diversity case such as this one, the Court applies federal procedural standards and state substantive law, including questions regarding the excessive nature of a damages award. See Imbrogno v. Chamberlin, 89 F.3d 87, 90 (2d Cir. 1996). In other words, "[t]he role of the district court is to determine whether the jury's verdict is within the confines set by state law, and to determine, by

reference to federal standards developed under Rule 59, whether a new trial or remittitur should be ordered." Gasperini v. Ctr. for Humanities, Inc., 518 U.S. 415, 435 (1996) (quoting Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 279 (1989)).

Therefore, the Court must look to Florida law in determining whether the verdict was excessive. In Florida tort cases, generally the Court is not to supplant the jury's damage calculation with its own. See Allis v. Boemi, No. 2D07-233, 2010 WL 3059445, at *4 (Fla. Dist. Ct. App. Aug. 6, 2010). As the Supreme Court of Florida has stated:

> Where recovery is sought for a personal tort . . . we cannot apply fixed rules to a given set of facts and say that a verdict is for more than would be allowable under a correct computation. In tort cases damages are to be measured by the jury's discretion. The court should never declare a verdict excessive merely because it is above the amount which the court itself considers the jury should have allowed. The verdict should not be disturbed unless it is so inordinately large as obviously to exceed the maximum limit of a reasonable range within which the jury may properly operate.

Bould v. Touchette, 349 So. 2d 1181, 1184-85 (Fla. 1977). Put another way, "[t]he verdict should not be disturbed unless it is so inordinately large as to obviously exceed the maximum monetary risk which the defendant should assume by its decision to litigate rather than settle a claim." Hawk v. Seaboard Sys. R.R., Inc., 547 So. 2d 669, 674 (Fla. Dist. Ct. App. 1989).

There is little utility derived from attempting to compare other damages awards to the verdict in this case to assess its reasonableness since ONJ is such a unique condition. The Boles action is the first Fosamax-related case to result in a plaintiff's verdict in this multidistrict litigation or otherwise. In a case filed against Novartis in Montana state court in which the plaintiff claimed to develop ONJ from a different bisphosphonate, the jury returned a $3.2 million verdict. However, as Mr. O'Brien acknowledged at oral argument on September 8, 2010, neither he nor the Court have enough information regarding the plaintiff's injury in the Montana case or the other underlying factual circumstances to knowledgably compare the two verdicts. Counsel points to other Florida cases in which courts have upheld multi-million verdicts to compensate for pain and suffering. See, e.g., Subaqueous Servs., Inc. v. Corbin, 25 So. 3d 1260, 1269 (Fla. Dist. Ct. App. 2010) (finding the district court did not err in upholding a $1.4 million award where plaintiff, a former fisherman, could no longer go on water due to a disc herniation which caused chronic back pain); Pierard v. Aerospatiale Helicopter Corp., 689 So. 2d 1099, 1100-01 (Fla. Dist. Ct. App. 1997) (reversing the trial court's order of remittitur on a $6.7 million award for pain and suffering where plaintiff sustained a fractured vertebra which resulted in a loss of bladder and bowel control, muscle spasms, depression,

and post-traumatic stress disorder). But for every case cited by Plaintiff, there are others in which Florida courts reduced more modest damage awards. See Kasper Instruments, Inc. v. Maurice, 394 So. 2d 1125, 1127 (Fla. Dist. Ct. App. 1981) (upholding the remittitur of a $150,000 verdict to $100,000 awarded to eighteen-year old woman facing "the prospect of continuous dental repair" for "severe dental injuries" causing "great physical pain and suffering").

Plaintiff did not introduce any evidence relating to her medical expenses, and thus economic damages are not at play. The evidence at trial established that Plaintiff has dealt with jaw complications for roughly seven years. She has developed draining fistulas under her chin, and her injury has hampered her ability to eat, leading to a considerable amount of weight loss. She certainly has endured significant amounts of pain, and the jury was able to see firsthand the consequences of her condition. According to her doctors, jaw surgery is likely. A significant damage award is warranted, but $8 million deviates substantially from what would be reasonable compensation.

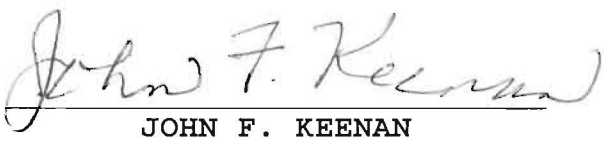
The Court hereby reduces the damage award to $1,500,000. Plaintiff has the option to reject the verdict. If she chooses to reject the reduced verdict, she is entitled to a new trial on the issue of damages.

III. Conclusion

Merck's motions for a new trial and for judgment as a matter of law are denied. Nevertheless, the Court believes the $8,000,000 verdict is excessive and orders a remittitur. Plaintiff has the choice between a new trial on damages and a reduced verdict in the amount of $1,500,000. Plaintiff shall notify the Court within twenty-one (21) days from the date of this Order whether she accepts the reduced verdict or chooses a re-trial on the issue of damages.

SO ORDERED.

Dated: New York, N.Y.
October 4, 2010



JOHN F. KEENAN
United States District Judge